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### U.S. advisers back 1st drug from DNA-altered animals

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By Susan Heavey

Posted 2009/01/09 at 8:21 pm EST

ROCKVILLE, Maryland, Jan. 9, 2009 (Reuters) — The first drug made using genetically engineered animals to near U.S. approval won key support on Friday from an advisory panel that judged it safe and effective despite concerns from groups worried about the genetic tinkering.

GTC Biotherapeutics Inc's experimental anticlotting therapy, called Atryn, is made using a human protein gathered from female goats bred to produce it in their milk.

GTC is seeking approval to sell the intravenous therapy to prevent excessive blood clots in patients with an inherited disorder.

Company data showed the drug was safe and effective, a majority of the [Food and Drug Administration's](#) 19-member panel voted. The FDA will consider the advice in making its decision, expected by February 7.

"This will... set a precedent for what will happen in the future," said [Dr. Richard Colvin](#), the panel's consumer representative and a clinical assistant in medicine at [Massachusetts General Hospital](#).

But some genetic-safety and animal advocates at the meeting expressed concern about the use of so-called transgenic animals despite the drug's benefits, saying more information is needed from the agency about genetically engineered animals.

The FDA issued preliminary guidelines in September about how it would regulate animals whose DNA has been altered and called for public comment, but it has not yet issued final details.

Approving Atryn "would be a back door way to approve transgenic animals," said [Jaydee Hanson](#), a policy analyst for the nonprofit group [Center for Food Safety](#).

Still, FDA officials said they were seeking advice on the specific product, not the larger issue of generically-altered animals. They added that the final regulations on such animals would be released soon.

Several patients and family members at the advisory meeting urged the FDA's approval of Atryn regardless of the transgenic issue.

[Karen Janes](#), whose daughter died after a 7-inch-long clot, said it could help her remaining daughter live longer and have children. "I don't care how it's made," the [New Mexico](#) resident told the panel.

Between 60,000 and 600,000 people in the [United States](#) have the excessive clotting disorder, known as hereditary antithrombin deficiency, according to GTC.

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GTC has estimated Atryn could generate up to \$40 million to \$50 million in U.S. annual sales in its first five years on the market. Shares of the company were halted Friday for news pending.

The goats used to make Atryn are bred using cells injected with human DNA. The company has a herd of about 200 at its [Massachusetts](#) facility, which are otherwise normal and screened for viruses, GTC said.

In a statement, company officials said the panel's vote helps get their key product closer to market. The drug is the biotech company's first therapy to reach the FDA for review.

Plasma derived products are also an option, but those are often in short supply and difficult for doctors to obtain for a variety of reasons, including the need for human plasma, the company and the FDA said.

"To me this is actually quite an exciting possibility that we actually can make much higher quantities ... that are easily accessible," panelist Colvin said.

The drug is licensed to [Ovation Pharmaceuticals Inc](#) in the United States.

(Editing by Tim Dobbyn)



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